NEGOTIATED RULEMAKING COMMITTEE ON THE SHARED RISK EXCEPTION

MINUTES[1]

September Meeting
September 9-10, 1997
Washington, D.C.

On September 9-10, the Negotiated Rulemaking Committee on the Shared Risk Exception held a negotiation session. (See **Attachment A** for a list of appointed Committee Members and their Alternates who attended the meeting.) The purpose of the meeting was to hear a presentation on the new Medicare+Choice program, to discuss options for resolving the "primary issues" identified at the July meeting, to identify reasons why Members could not concur with particular proposed options, and to determine the next steps in the negotiations.

The meeting was noticed in the Federal Register and was open to the public. The meeting was held in the HHS Cohen Building in Washington, D.C.

FIRST DAY, SEPTEMBER 9, 1997

Facilitator Judy Ballard introduced Jeff Sacks (who was assisting her in the absence of her co-facilitator), asked Committee Members/Alternates to introduce themselves since there were some observers, and then reviewed the proposed meeting agenda.

Presentation on Medicare+Choice Program

Tracy Jensen of HCFA's Center for Health Plans and Providers gave an overview of the Medicare+Choice program under a new part C of title XVIII of the Social Security Act (Act), as enacted in the Balanced Budget Act of 1997 (BBA). She explained, among other things, that a Medicare+Choice plan may be: A) a coordinated care plan; B) a combination of a Medicare Savings Account (MSA) plan and contributions to a Medicare+Choice MSA; or C) an unrestricted private fee-for-service (FFS) plan. A

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[1] These minutes were prepared by the facilitators for the convenience of the Committee Members and should not be construed to represent the official position of the Committee or of any Member on what transpired at the meeting.

coordinated care plan is a plan that provides health services and could include: 1) health maintenance organization (HMO) plans (closed provider networks, with or without point of service options); 2) plans offered by a provider-sponsored organization (PSO); and 3) preferred provider organization (PPO) plans (fee-for-service plans with incentives to use network providers). A coordinated care plan could be an HMO already contracting with HCFA under section 1876 of the Act on a risk basis, but the plan would no longer have to meet the 50/50 (Medicare/commercial) enrollment rule. Otherwise, section 1876 contracts will be phased out, with no provision under Part C for cost-based contracts.

Except for MSA plans, each Medicare+Choice plan must provide all Part A and Part B benefits to enrollees in exchange for a capitated rate. To be a Medicare+Choice organization, an organization must be a public or private entity that is certified by HCFA as meeting specified requirements, including quality of care requirements. Organizations that are certified as meeting these requirements may contract with HCFA. Except for certain PSOs, a Medicare+Choice organization must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage.

A PSO is defined (in section 1855(d) of the Act) as "a public or private entity"--

- that is established or organized and operated, by a health care provider, or group of affiliated providers,
- that provides a "substantial proportion" of the health care items or services directly through the provider or affiliated group of providers, and
- with respect to which the affiliated providers share "directly or indirectly, substantial financial risk with respect to the provision of such items or services" and have at least a majority financial interest in the entity.

Any coordinated care plan that has a physician incentive plan (PIP) that places a physician or physician group at "substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group," must meet certain requirements.

An FFS plan (FFS Panel) would be reimbursed on a capitated basis from HCFA and then reimburse providers on a fee-for-service basis, but the reimbursement rates could not vary based on utilization. The plan would not be allowed to put the providers at risk, but could get discounts from the provider's usual and customary rates.

Discussion of Potential Relevance for Committee Negotiations

After the presentation, the Committee discussed the following:

- Whether a technical amendment to section 216 of HIPAA (the Shared Risk Exception) would be proposed by the Secretary since section 216 refers to "eligible organization under section 1876" and the BBA does not address the effect of phasing out the 1876 contracting program and substituting a new one, but does require the Secretary to propose conforming amendments.

- Whether the references to "substantial financial risk" in the new Part C are relevant for determining what is "substantial financial risk" for purposes of the Shared Risk Exception.

- Whether the new legislation otherwise affects the negotiations.

The HHS/IG representative indicated that he was not aware of any proposed technical amendment. He said that the IG would not read the reference to "eligible organization under section 1876" broadly to encompass all Medicare+Choice organizations. He indicated that the test concerning whether to provide protection for Medicare+Choice contractors similar to what is in effect for section 1876 contractors would be whether the purpose of preventing overutilization would be met by broadening the first part of the exception. He indicated that this issue had not been fully evaluated and that there was some concern in particular about protecting FFS Panels and PPOs. He then addressed the broader question about the scope of Committee negotiations. He noted that the notice of intent to negotiate had indicated that the scope was limited to what was protected under section 216 of HIPAA (rather than extending to existing or new safe

harbors). He stated, however, that he was amenable to hearing Committee Members' views on the broader policy issues, such as whether the personal services safe harbor should be amended, not as issues to be resolved in a section 216 rule, but as a potential subject for a future rulemaking. He said that he recognized that section 216 may cover only part of the managed care arrangements that should be protected.

Several Committee Members expressed concern about the possibility of there being no conforming amendment to section 216, which could mean that any Committee consensus could not cover a large portion of the managed care arrangements. One Member noted that even FFS Panels and PPOs would be capitated under the new program, which would appear to meet the anti-kickback concern.

With respect to the references to "substantial financial risk" in the new legislation (see **Appendix B for these provisions, with additional context**), one Member expressed concern that definitions of the term for purposes of the new Part C program might have an effect here, given that some had suggested that the current PIP rule definition should be used as a benchmark. Others indicated that this should not be a concern, since (like the current PIP rule) the context and purpose is different. No one appeared to disagree with this.

There was some disagreement, however, about the relevance of the FTC antitrust approach to "substantial financial risk." One Member said it was irrelevant because the FTC policy does not have the anti-kickback goal of stopping overutilization and, therefore, permits a provider to order as many services as possible. The opposing view was that the FTC approach is intended to be flexible about letting a new product enter into the market to enhance competition (so long as the combinations would not drive the price up), and that the goal of the exception is similarly to facilitate the formation of certain types of organizations, so long as there is no abuse. Even if FFS is involved, another Member said, abuse can be prevented if the organizations are bidding against each other for patients.

Discussing Options for Resolving the Primary Issues

The facilitator then explained that the purpose of discussing options at this meeting was to achieve

consensus on broad concepts, if possible. If a Member did not concur in an option being discussed, the Member would have the responsibility of stating reasons (underlying needs and concerns), which would then be recorded and used to generate new options. Resolutions will have to take all needs and concerns into account. She noted that, in addition to the options that had previously been submitted to her and distributed to the Committee, two other sets of options had been distributed that morning. (All of these options are included in the document at **Appendix C**. These minutes refer to those options by Issue Group designation, such as *Group, and number, rather than by identifying them to any particular Committee Member. The minutes below include new or modified options generated during the meeting, as well as consensus items, and these are also included in **Appendix C**, along with consensus items from the July meeting.)

~GROUP

The Committee first discussed the ~Group (About Group) of issues and reached the following **CONSENSUS:**

> For purposes of this rule, there is no functional difference between a withhold and a bonus.

****GROUP***

The first two issues in the *Group (Star Group) are:

* *Does the language of the law (exception) cover anything but the top relationship between MCO and first level contractor?*
* *What constitutes an "organization"? (Can it be a provider? an IPA?)*

The Committee generally discussed these issues as relating to whether the exception protects risk sharing arrangements "downstream" from the "first tier" relationship between an MCO and individual or entity providing items or services, or a combination thereof. One Member began the discussion by suggesting that you look at it from the bottom up, rather than the top down, so that you'll be OK if anyone below you is at substantial financial risk.

Another sought to clarify whether the Committee was addressing the first part (first prong) of the exception or the second prong. After that, Members tried to distinguish when they were addressing the first prong and when the second.

The major concern expressed with respect to the **first prong** related to the statutory language of the first prong, which protects--

> remuneration pursuant to a written agreement **between** an organization and an individual or entity providing items or services, or a combination thereof, where the organization is an eligible organization under section 1876 . . . .

One Member said that an "eligible organization" has to be an organization with a Medicare contract, so the first prong could not extend to remuneration between any other "organization" and a provider.

The Committee then began to consider the **second prong** of the exception and to identify the needs/concerns of those who nonconcurred in **combined Options 3 and 4 in the *Group**: briefly, only the top relationship between the MCO and first level contractor qualifies; "organization" means a "health plan" as defined under current safe harbors. Those **needs and concerns** were that--

- this would exclude most existing risk sharing arrangements;
- the market may be better off if you allow flexibility;
- discouraging subcontracting would encourage aggregation into one level;
- the effect would be that no risk would be assumed at the provider level where there is the most opportunity to manage risk and control costs;
- reserving protection for the "first tier" would not provide a safe harbor for those at lower levels;
- most health plans are already covered under the pre-paid plan safe harbor;
- if lower levels have no incentive to manage risks, this undermines the effectiveness of first tier arrangements;
- the term "health plan" would need to be defined (need to figure out new definition proposed);

- a majority of provider types would have their arrangements unprotected.

There was also considerable discussion of whether there needed to be substantial financial risk at the first tier in order to protect downstream arrangements. One health plan representative said she could not imagine the situation where there was risk below, but not risk above, but one provider system representative asked what about a plan paid on an FFS basis with capitated payments lower down? A law enforcement representative expressed the **concern** that what happens at tier one will make a difference with tier two and tier three. Specifically, he said that letting any provider be an "organization" would give rise to a real **anti-kickback concern** because providers paying kickbacks to one another can have contracts with each other that look like risk sharing but are really referrals because the providers control the "target utilization." He said there needs to be a tie to the first tier or otherwise the target can be set artificially low or high and there is no risk sharing arrangement.

Other Members acknowledged the legitimacy of this concern although some said that the potential for this abuse can exist at any level. One Member said basically: if it's a sham, it's a sham, and if you can't show that the risk is "real," you do not qualify for the exception. The test, he suggested, should be whether the arrangement accomplishes the goal of preventing overutilization. He also expressed some concern, however, about whether the proper incentives occur if there is no risk sharing at the top.

There were differing views on whether fitting into the form (but not the substance) of a transaction would be sufficient to qualify for protection. Other Committee Members suggested defining substantial financial risk so that sham transactions cannot qualify. One Member suggested that a **possible resolution** would be **to define substantial financial risk to make sure that the risk is actuarially valid risk.** Another made the **process suggestion** that once the Committee had a model, the Committee could think of ways to subvert the model.

The Committee did not reach consensus on this issue since one health plan representative indicated that he would

prefer not now saying that, if there is no risk on top, there is none below.

After lunch, a representative of the long-term care industry indicated that he did not like to keep putting off resolving whether the exception could apply below the first tier arrangement. If this issue is not negotiable, he said, he would not need to be here, and this would leave the state of the law as it now stands, which is very confusing for his constituents.

The facilitator asked the law enforcement representative promoting the limit to "health plans" to give her reasons. Statutory construction was given as the basis for the position, under the rationale that the language in the first part of the exception refers to "eligible organizations under section 1876", which are health plans, and therefore, in context, the term "organization" should also be read as referring to health plans. A health plan representative stated that he could understand this statutory construction argument, but suggested that, from his experience, the term "organization" is not a term of art, even in this context. He suggested that the Committee should ask: "What are the array of legally permissible interpretations that we can choose that are most consistent with the purpose of the statute?" Looking at the statutory purpose of allowing a full range of risk sharing arrangements, he said, would support a broader interpretation because otherwise a majority of the risk sharing arrangements would not be protected. A physician representative noted the broad meaning of "organization" in the health care industry. Another Member read from the legislative history of the shared risk exception, giving his opinion that the legislative history supports a broader interpretation.

The facilitator then asked how the Committee would address the concern of the Committee Member who wondered why he was here if the issue of what is an organization is arguably off the table. One Committee Member said that, if organization only means health plan, three fourths of the Committee Members could go home, and that there would be no need to define substantial financial risk since the prepaid safe harbor addresses most pre-paid health plans.

The facilitator raised a process concern, noting that (as the convening report had said) it is important in a

negotiated rulemaking that an agency identify any issues that are outside the scope of the negotiations before the negotiations begin, so that Committee Members know before they commit their resources. She noted that the issue of what is an "organization" had not been identified as such an issue. The proponent of the "health plan" definition then indicated that the issue is **not off the table.**

She further said that, while she could not conceive of a situation where the first prong (which does not implicate risk sharing) could be read as applying to lower tiers, there was less clarity as to the second prong. After the language of the exception was displayed, however, she did clarify that **levels downstream from the 1876 organization could be protected by prong two.** No one expressed disagreement with this.

There was then further discussion of whether all arrangements downstream from the 1876 organization in a full capitation model should be protected. One Member noted that Option 6 in the *Group is: The exception covers each contracting tier from the MCO (or other payor) through to the provider of services. The HHS/IG representative acknowledged the strength of this argument, indicating that the IG would be looking to clarify this for other safe harbors, but pointing out that not all 1876 contracts are risk contracts--some are cost-based.

All Committee Members present except one concurred that only the first tier relationship would be protected under the **first prong**. The nonconcurring Member reserved concurrence, indicating a need to consult with constituents. A Member then asked for clarification of whether the first prong would cover a Federally Qualified HMO (FQHMO), even if the FQHMO did not have a Medicare contract with HCFA. The Committee reached **CONSENSUS** that--

> An FQHMO does not have to have a Medicare contract to be an "eligible organization under section 1876."

Returning to the **second prong**, the Committee clarified that there were the following three **options** for resolving this issue:

> **A.** Only a health plan can be an "organization"

B. Each contracting tier from the MCO (or other payor) through to the provider of services would be protected.

C. Lower tiers could be protected, but only if protected above.

Having previously identified **needs/concerns** for the first two options, the Committee identified the following for **Option C**:

- How do you check whether higher tiers are protected, especially if you are at the fourth or fifth tier?
- [What protection does this add given what] is already covered by existing safe harbors?
- Attorneys might not be able to give any opinion that an arrangement would be protected.

The Committee decided to set aside whether it is significant whether risk is assumed higher up, until the Committee examines specific arrangements. Additional **concerns** for either approach were identified:

- Will the approach have an unintended effect in the marketplace and lead to inappropriate arrangements?
- Will the standard for protection be so high that it affects quality?

The third issue in the *Group was then discussed separately from the others since some Members did not agree with the premise of the issue. Members reached **CONSENSUS** that--

> Even if the exception only applies to the first tier, it does not mean that the downstream arrangements are necessarily kickbacks. Simply because something does not fall within a safe harbor does not mean that it is per se illegal.

Q GROUP

Beneficiary representatives asked to discuss how to address a quality concern in the rule, for example, questions such as:

- If too small a group is capitated or if an incentive is tied too closely to an individual's treatment and

services are poor, should it be treated as a kickback?
- Are there corridors of capitation or types of incentives that are beyond the pale?
- Are some types of risk "shoving" onerous?

Option A (written agreement must include incentives to meet quality standards) was discussed and the following **needs/concerns** identified:

- This would affect many existing contracts that do not contain such incentives.
- This would be too complicated, and PIP rules already address underutilization, the flip side of the overutilization that is the anti-kickback concern.
- There are already a host of protections and laws (Quality Outcome Measures), some of which have given rise to a private right of action, so providers would be "gun shy" about adding new ones.
- This would mean less flexibility in the marketplace under the False Claims Act.
- How would you evaluate what's an appropriate incentive, especially if no quality standard exists other than accepted community practice?

One beneficiary representative later said that **Option 1 could be modified** so that the incentives could merely incorporate existing standards, rather than adding new ones.

An option discussed as **Option B** (not previously proposed) is to address quality concerns as part of defining what is "substantial financial risk"--by not setting the level too high or by requiring that something be in the contract if the level is set high so as to cause a concern for underutilization.

Option C (proposed as Option 2 on Appendix C) is to say that, if a provider is out of compliance with a quality standard, the exception would not apply. Some Members strongly objected to this option, identifying the following **needs/concerns**:

- If you link protection to compliance with quality standards, protection could be lost for one minor procedural noncompliance.
- Providers are subject to multiple audits already.
- There are no standards for doctors.

This led to the suggestion for **Option D:** the written agreement would include incentives to meet existing standards. The reaction was that this would still not address a **concern** that this would add another group of people interpreting quality standards and cause problems if they interpreted the standards differently. It was noted that there are already conflicts caused if standards imposed by an MCO are different from applicable State or Federal standards.

One Member suggested **Option E:** If there is an existing law or accreditation standard that applies to the provider, accept that; require that there be an incentive in the written agreement only where no existing law or accreditation standard applies; also, you would not need an incentive for any group that contracts with an MCO that is accredited or subject to existing laws on quality, because the MCO would have an obligation to ensure that quality standards were met. Members identified as **needs/concerns** for this option:

- This would be tough to apply - what do you measure against?
- What do you need to look at to see whether you are protected?

Option F is to add nothing new, but to say that the overall quality test would be whether the arrangement provides an incentive to overutilization. The following were identified as **needs/concerns** for this option:

- The major consumer concern with the exception is underutilization.
- This assumes that all levels are healthy and that the entity will ensure that appropriate care be provided.
- Congress identified "the extent to which the risk sharing arrangement provides an incentive to control quality of care" as a factor to be taken into account, which shows a concern with more than just overutilization (but does not necessarily mean that quality standards are required).

Option G is to have in the rule that quality of care oversight must flow down. The following were identified as **needs/concerns** for this option:

- What happens if you do not have any quality standards that apply?
- What if there is a conflict between the MCO's standard and a Federal standard?

One representative of the pharmacy industry noted that no quality standards apply to the formulary arrangements at issue there, so he would not object to some quality requirement there in order to get protection.

+GROUP

The +Group of options (Plus Group) address primarily what is a risk-sharing arrangement (RSA), and whether straight capitation constitutes risk sharing. The discussion resulted in a **QUALIFIED CONSENSUS** on what was identified as Option 1 for the +Group, was modified during discussion, and concurred in--with the understanding that some questions remained. The **modified option** is:

> A risk sharing arrangement is one in which at least some "real" risk is transferred to or shared with a second party. The first party need only retain ultimate liability for the services. For example, in a straight capitation from an MCO to a capitated primary care provider, almost all of the risk for primary care services has been transferred to the provider. However, if the provider fails to provide the required care under the agreement with the MCO, the MCO remains responsible to find another provider to provide primary care services.

The **remaining questions that qualify the consensus** are:

- Does risk sharing include being "at risk"?
- How could a capital contribution be a sharing of risk?

While it was noted that section 216 mentions the degree of capital contribution as a factor to be considered, none of the Committee Members present said they knew the reason for this. One suggested that capital contribution might go to the idea of preventing "sham" arrangements.

The meeting was adjourned for the day at about 5:00 p.m.

SECOND DAY, SEPTEMBER 10, 1997

The Committee reconvened at about 9:00 a.m. on September 10, 1997.

Identifying Additional Needs/Concerns Related to Options Previously Discussed

The facilitator began by asking if Committee Members had additional **needs/concerns** related to the options considered the day before, and the following were listed:

- The need for the Committee to be clear which prong it is addressing at any point in time;
- A primary concern being to make sure downstream arrangements are protected;
- A caution regarding adopting particular quality standards where there is a continual improvement process in developing standards;
- A concern with making sure that the rule does not diminish quality;
- A concern that in order to make Medicaid managed care work the top tier will have to find someone down the line to accept capitation;
- A concern about cost from the consumer perspective: what effect the rule will have on affordability;
- A concern about adding quality requirements where existing standards already raise problems with proprietary information; and
- A concern that quality not suffer--not necessarily adding new standards, but no disincentive to quality.

Some Members also commented on how productive the previous day had been. Several made a **process suggestion** that the Committee should focus on particular practices that should be protected and those that should not be protected--for example, in discussing rebates, it might help to find out what people want to protect and to discuss whether rebates are OK if coupled with financial risk or a kickback.

Discussing Options for Resolving the Remaining Groups of Issues

>GROUP

The Committee first addressed the issue from the >Group (Greater than Group): what items and services, or combination thereof are covered by the exception, in light of the language **"obligated to provide."** The Committee agreed that this is a **second prong** issue only. **Three categories** of possible covered items and services were identified and clarified, with two subcategories for Category 3, as follows:

Category 1. Those the individual or entity provides directly by employees.
Category 2. Those the individual or entity is financially responsible for (including subcontracts if the individual or entity pays the subcontractor, the MCO pays the subcontractor on behalf of the individual or entity, or the subcontractor is paid by reinsurance the individual or entity has obtained).
Category 3. Those for which the individual or entity does not receive payment but for which the individual or entity may be rewarded:

> **Subcategory A.** Those where there is a close relationship between the compensation the individual or entity receives and particular items or services.
> **Subcategory B.** Those where compensation is tied collectively to efficiencies.

One Member noted that the PIP rule says that the types of incentives in both subcategories are included in determining whether there is substantial financial risk.

The Committee reached **CONSENSUS** that the items and services in **Categories 1 and 2**, as described above, are covered by the phrase "obligated to provide".

Committee Members who did <u>not</u> concur in including Category **3** listed the following **needs/concerns if Category 3 is covered**:

- Are these items and services captured within the words of the exception (even if there is a relationship from the policy perspective)?
- The exception would be harder to apply to this category if there is no bright line test for what constitutes substantial financial risk.

Committee Members who wanted Category 3 to be included expressed the following **needs/concerns if Category 3 is not covered**:

- This might push physicians into arrangements for which they are not ready;
- This would make it more difficult to align incentives (for example, medical group/program);
- Groups have to balance FFS/MC work in putting together salary structures;
- Need to create cultural integrity;
- Have to consider individual's outcomes as part of a program to manage costs;
- Need to balance many things in determining an appropriate compensation strategy, including self-referral and PIP laws;
- Bundling of nursing home reimbursement is a natural tie-in to risk-sharing--since SNFs now must bill for all services (except physician services), they need to subcontract.

One Member suggested that an **option** to either including or excluding Category 3 would be to include subcategory A, but not subcategory B. **Concerns** with this option were:

- Provider incentive plans being developed are usually a combination of the two subcategories; and
- Some provider groups (especially physicians or those in rural areas) are not ready to take on full financial responsibility for all services and you do not want to push them into arrangements they are not ready to handle.

The Committee then turned to the issue in the >Group of **whether the items and services must be medical**, identifying the answer "No" as **Option 1** (for resolving this issue with respect to the **second prong of the exception)** and the following as **Option 2** for the second prong:

> The services must be health services or reasonably related to the provision of health services (which would include patient education, attendant social services like case management, and disease management).

Needs/Concerns of those nonconcurring in **Option 2** are:

- What does "reasonably related" mean? -- could it include a trip to an exotic place as a reward for performance?
- Would marketing be specifically excluded?
- Would things like software programs, in-service training, and infection control be included, or called marketing instead?
- What if what you receive has a broader application to FFS patients? Could you allocate between FFS and MC patients? Would there be a "pull-through" effect?
- Is this broad enough to encompass gatekeeping functions, which should be included?
- When would there be a potential kickback?

During the discussion, it was noted that there is a stronger argument that the **first prong** of the exception covers all items or services, including marketing fees, than for the second prong, where there has to be "substantial financial risk for the cost or utilization" of the items or services. The **concern** of those who want to cover marketing fees is that it is important to have independent agents help consumers to compare plans. The **concerns** of those who want to exclude coverage are that there have been marketing abuses (particularly in Medicaid), and that, as a policy matter, the MCO would have more responsibility for what a marketer is saying if the marketer is under the MCO's supervision. One representative of health plans described two opposing views: (1) that supervision by the MCO is better; and (2) that the independent agent has the consumer, rather than the MCO, as the client, and this is better.

Another **issue in the >Group** that was mentioned was the question of whether the services need to be **medically necessary** services. A question had been raised about where in the statutory language this idea was. The Committee did not fully discuss this issue. Also, part of one issue in this group (whether the services needed to be listed in the agreement) was moved to the #Group of issues related to defining "written agreement".

•GROUP

After lunch, the Committee took up the •Group (Bullet Group) of issues, first addressing: *What is the effect of pooling risk on whether it's "substantial financial risk"*? One Member gave the following view. If you aggregate lives across plans or product lines, the amount

of risk is reduced. This is recognized in the PIP rule, which allows for less comprehensive stop-loss protection if more lives are involved. The more you aggregate, the more risk can be assumed because the risk becomes more predictable. On the other hand, to promote efficient delivery, you want the risk to have an impact. If you have ten doctors' groups, one of which is doing poorly, there is less incentive for them to improve if there is pooling of risk and the others do well.

Another Member expressed the **concern** that if you make the exception broader, to encompass pooling, the arrangement might include one risky deal (that seemed to be substantial financial risk) and one "sweetheart" deal that meant the risk was not real. The question was raised: "Risk of what?--risk of providing more services or risk of losing money?" One law enforcement representative said that **prong 2** refers to a single written agreement, so the substantial financial risk and risk sharing would have to come within the framework of a single written agreement. There was no concurrence about this.

This led to a discussion of the option of saying that each arrangement had to involve substantial financial risk, and this became the **modified option**: the risk within each written agreement must be substantial financial risk. The Committee reached **Qualified Consensus** to adopt this option. One Member who qualified his concurrence said that it would depend on what is encompassed within "items or services," but that he may concur if the items or service must be "reasonably related", as discussed earlier. Others expressed a concern with making sure that the wording would not exclude the risk a small entity assumes where there is pooling, for example, if a small rural entity has multiple agreements. Small entities might need to pool risk in order to obtain access to stop loss insurance. There was also concern about whether one contract covering services provided at seven different facilities would be covered. One Member noted that the statute says to take into account the size and type of the arrangement.

The following questions were also raised: What happens if there is only one written agreement, but the chance for a bonus depends on the overall performance of either the HMO or other providers? Is this out because the

items or services are not ones the individual or entity is "obligated to provide"? Can you calculate that factor in? How do you take into account the impact on the individual provider? How do you take into account the size and type of the provider?

The Committee then discussed whether the definition of "substantial financial risk" (SFR) should be in numerical or nonnumerical terms. **Needs/Concerns of those who could not concur in defining SFR in numerical terms** are:

- This does not take into account differences among providers.
- The evolution in the marketplace is significant and happening in a short time frame--numerical standards would keep the market from evolving.
- Any numerical approach would be crude and not be a sophisticated surrogate for what actuaries use to define risk.
- The acceptability of a numerical standard would depend on what it is a factor of--% of revenue of all kinds (versus revenue from the specific contract) is unacceptable.
- It would be hard for the Committee to do it: there would have to be subcategories (depending on type of providers, e.g. rural, and types of risk, e.g. capitation payments); this would be complicated; and this would be difficult to make clear.
- The lack of flexibility would cause market distortions.
- The Committee may not have the expertise to do this; it would make the whole process take longer and require a primary research project since the data to make it work does not exist.
- Numeric standards might be set higher than what is necessary to be effective.
- The existing PIP numeric standard does not fit here.
- PIP has a different purpose.
- The Committee would first need to pick a methodology, such as the PIP percent for referral services and a different percent for others.
- If a bright line is set, leaving a gray area, this leaves people trying to comply with the law without any legal standards/principles to guide them and, in effect, means that arrangements outside the bright line will be treated as illegal; with no legal principles, the matter is left to prosecutorial discretion.

The following were identified as **needs/concerns if a nonnumerical standard is used:**

- How could a lawyer give a clean opinion if there is not enough certainty regarding what the exception covers?
- In the criminal law arena, clarity is particularly important because guilt will be decided by a jury.
- The major criticism in the anti-kickback area in the past has been that it's too gray; this is an opportunity to tell people what's legal and that is what Congress intended in requiring that the rule establish standards.
- A nonnumerical standard would not meet law enforcement needs.

The Committee then identified some **new options**. **New Option A** is to say that any risk that is downside (foregoing something that the individual or provider might otherwise be entitled to, such as an agreed to fee) would be considered substantial. The **concern** expressed with this option was the view that any distinction between downside and upside risk is meaningless. One Member pointed out that the Committee had already reached consensus that functionally, there is no distinction between bonuses and withholds. Another problem with this approach, one Member said, would be that the downside risk may be too small to provide any incentive.

New Option B has two components: 1) have a requirement for a bonus, withhold, or other incentive for efficient behavior and state the principles behind this; and 2) include an element to add credibility (for example, actuarial soundness to prevent a "sham")--a recognizable standard. A Member expressed a **concern** that the Committee may be talking about things it does not understand. The facilitator noted, however, that Committee Members had indicated during convening that they were willing to commit the resources to make the process work, which could include obtaining technical expertise.

New Option C is a hybrid test that would construct a bright line test to protect some arrangements, and then set out principles that could be used to analyze other arrangements (for example, whether the arrangement is commercially reasonable). This would reflect the antitrust approach, one Member said.

New Option D would look at the intended purpose and effect of the arrangement regarding cost and quality, and then look at the actual effect of the arrangement, setting out factors for analyzing it. A **concern** was raised by a law enforcement representative that this would be too hard to prove. One Member commented that an argument that an exception applies could be viewed as an affirmative defense that the proponent of the argument would have to prove, rather than the law enforcer. He also noted that juries do apply nonnumeric standards, such as in complex securities cases.

New Option E was described as two parts, with capitation covered and a "quantity-based" test, the purpose of which is to define the degree of incentive needed to prevent overutilization, which could vary by type and size of provider. The proponent of this option acknowledged that quantity-based probably meant numeric (but varying the test according to type and size could address concerns with using a single numeric standard). He also acknowledged that a percent like 25% (from PIP) would be ridiculously high for hospitals. **Needs/concerns** identified for this option were that a bright line test would drive the market and that nobody knows what the bright line should be.

New Option F was a combination of: A. Bright line tests that you could meet to be protected; and B. A series of factors that, if met, would also protect the arrangement.

Several Members then pointed out that, however the Committee defines SFR, the Committee will have to explain what it did and why. This led to a discussion of a **process** by which part of the Committee could generate details of an option or options for numerical tests and another part of the Committee could generate a nonnumeric option or options. As a result of this discussion, the Committee concurred that--

- Between now and the October meeting, Members interested in developing numeric options will meet in caucus and Members interested in developing nonnumeric options will meet in caucus.

- At the start of the October meeting, Members will call a caucus, so that the two groups can continue

discussion with the Members from out of town before presenting the options to the full Committee.

- The Committee will reconvene at 1:00 to have the options presented and discussed.

The Committee also discussed obtaining some actuarial assistance, possibly by telephone or telephone conference, from actuaries of the NAIC or the American Academy of Actuaries.

@GROUP

The Committee then discussed the @Group (At Group) of issues. Most Members present concurred **conditionally to adopt Option 1**: To be covered by the exception **(second prong)**, the specific items or services provided must be covered by a risk sharing arrangement. (No consensus could be reached since there was no longer a quorum).

The **concern** was expressed that concurrence would depend on what falls within the definition of a risk sharing arrangement. One Member representing pharmacies stated that he could not concur because his constituency provides services under a capitated umbrella by getting discounts and rebates, and it was unclear whether they would qualify as risk. A Member representing law enforcers said that items or services not within a risk sharing arrangement simply would no fit under prong 2.

#GROUP

Finally, the Committee addressed the #Group (Pound Group) of issues, and the related issue moved from the >Group (see above), concerning what is a "written agreement."" **Option 1 was modified to read**:

A written agreement must meet the following requirements:

(1) set out in writing and signed by the parties
(2) specifies the items and services covered by the agreement
(3) specifies the intervals at which distributions will be made
(4) specifies the formula for calculating incentives/penalties
(5) lasts at least one year

> (6) the methodology for determining compensation is set in advance, is consistent with actuarially sound calculations in arms-length transactions, and is not determined in a manner that takes into account the number of Federal fee-for-service beneficiaries being served under the contract.

One proponent of the option explained that the last part was intended to address the problem of "pull through," but might not be needed if the items and services must be covered by the risk sharing arrangement. The following **needs/concerns** were identified:

- What does "specifies" mean with respect to items or services? If you have to list everything in a package of services, this would be too much.
- What does it mean that the methodology must be consistent with actuarially sound principles? Could you take this into account in the definition of "substantial financial risk" instead?

The Member who raised the first concern suggested an **option** that there be a general descriptor of the services, which would be sufficient to define the services according to community standards.

The meeting adjourned at about 4:45 p.m.

Next Meeting

The next meeting will start October 8 at 9:00 a.m. and go until 2:00 p.m. on October 10. The meeting will be held in the same place as the September meeting: the OIG conference room, Room 5542, of the Cohen Building, entered on C Street, S.W., between 3rd and 4th streets. Anyone other than a Committee Member or designated Alternate who wishes to attend should call Joel Schaer at 202-619-0089 by at least the day before the meeting to facilitate entry into the building. The Committee will continue discussing options for resolving the remaining primary issues, including options generated by groups of Members in caucus using the process described above.

ATTACHMENT A - LIST OF PARTICIPANTS

Committee Members present for part or all of the meeting:

Cheryl Matheis, American Association of Retired Persons
Ken Burgess, American Health Care Association
Mary R. Grealy, American Hospital Association
Edward B. Hirshfeld, American Medical Association
Brent Miller, American Medical Group Association
Susan E. Nestor, BlueCross BlueShield Association
Charles P. Sabatino, Consumer Coalition for Quality Health Care
Missy Shaffer, Coordinated Care Coalition
Laura Steeves Gogal, Federation of American Health Systems
Eddie Allen, Health Industry Manufacturers Association
Kylanne Green, Health Insurance Association of America
Fred Nepple, National Association of Insurance.
Stephen M. Spahr, National Association of Medicaid Fraud Control Units
Michael Weiden, National Rural Health Association
J. Mark Waxman, The IPA Association of America
Karen A. Morrissette, Department of Justice
D. McCarty Thornton, Department of Health and Human Services Office of the Inspector General

Alternate substituting for Committee Member:

Mark Gallant, NACDS
Marjorie Powell, PhRMA
Mark Joffe, AAHP
Janet Stokes, IIAA/NAHU/NALU

Alternates attending and/or substituting for Committee Member for part of the meeting:

Sandy Teplitzky, AHCA; Kathy Nino, AMA; Mary L. Koffner, AMGA; Julie Simon Miller, BCBSA; Jonathon M. Topodas, CCC; Brent Philips, TIPAAA; Bob Wallace, DOJ; Priscilla Shoemaker, AHCA.

ATTACHMENT B

Balanced Budget Act Excerpts

SEC. 4001. ESTABLISHMENT OF MEDICARE+CHOICE PROGRAM.

Sec. 1852(j)

(4) LIMITATIONS ON PHYSICIAN INCENTIVE PLANS.--
(A) In general.--No Medicare+Choice organization may operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:
(ii) If the plan places a physician or physician group at **substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group**, the organization--
(I) provides stop-loss protection . . . and
(II) conducts periodic surveys . . . .
(B) Physician incentive plan defined.--In this paragraph, the term `physician incentive plan' means any compensation arrangement between a Medicare+Choice organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization under this part.

Sec. 1855. (a) ORGANIZED AND LICENSED UNDER STATE LAW.--
(1) In general.--Subject to paragraphs (2) and (3), a Medicare+Choice organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Medicare+Choice plan.

* * *

(d) PROVIDER-SPONSORED ORGANIZATION DEFINED.--

(1) IN GENERAL.--In this part, the term `provider-sponsored organization' means a public or private entity--
(A) that is established or organized, and operated, by a health care provider, or group of affiliated health care providers,

(B) that provides a substantial proportion (as defined by the Secretary in accordance with paragraph (2)) of the health care items and services under the contract under this part directly through the provider or affiliated group of providers, and

(C) with respect to which the affiliated providers share, directly or indirectly, **substantial financial risk with respect to the provision of such items and services** and have at least a majority financial interest in the entity.

(2) SUBSTANTIAL PROPORTION.--In defining what is a 'substantial proportion' . . . the Secretary--

(A) shall take into account the need for such an organization to assume responsibility for providing--

(i) significantly more than the majority of the items and services under the contract . . . through its affiliated providers; and

(ii) most of the remainder of the items and services . . . through providers with which the organization has an agreement to provide such items and services, in order to assure financial stability and to address the practical considerations involved in integrating the delivery of a wide range of service providers;

(B) shall take into account the need for such organization to provide a limited proportion of the items and services under the contract through providers that are neither affiliated with nor have an agreement with the organization; and

(C) may allow for variation in the definition of substantial proportion among such organizations based on relevant differences among the organizations, such as their location in an urban or rural area.

(3) AFFILIATION.--For purposes of this subsection, a provider is `affiliated' with another provider if, through contract, ownership, or otherwise--

(A) one provider, directly or indirectly, controls, is controlled by, or is under common control with the other,

(B) both providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986,

(C) each provider is a participant in a lawful combination under which each provider shares **substantial financial risk** in connection with the organization's operations, or

(D) both providers are part of an affiliated service group under section 414 of such Code.

(4) CONTROL.--For purposes of paragraph (3), control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance rights of another.

(5) HEALTH CARE PROVIDER DEFINED.--In this subsection, the term `health care provider' means--

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(6) Regulations.--The Secretary shall issue regulations to carry out this subsection.

Shared Risk Exception language from §216 of HIPAA:

substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide

ATTACHMENT C

Revised Options for Resolving the Primary Issues

*** GROUP OF ISSUES**

First two issues:

* *Does the language of the law (exception) cover anything but the top relationship between MCO and first level contractor?*

* *What constitutes an "organization"? (Can it be a provider? an IPA?)*

Options developed before the September meeting:

*1 If the primary agreement between an organization and an entity does not meet the criteria that qualify it for the exception, subordinate relationships may still qualify for the exception if they meet the criteria.

*2 An entity may simultaneously also be an organization even if it has a downstream agreement with another entity.

*3 The exception does not cover anything other than the top relationship between the MCO and the first level contractor.

*4 An organization could be defined as a "health plan" under the current safe harbors -- "an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity: (i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program; (ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations; (iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or (iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market price of those services." 42 C.F.R. § 1001.952(l)(2).

***GROUP (cont.)**

*5 If the exception applies to the primary agreement between an organization and an entity (usually an agreement between a managed care company and a provider group), the exception should also apply to all agreements that are subordinate to the primary agreement.

*6 The exception covers each contracting tier from the MCO (or other payor) through to the provider of services

*7 As used in the second part of the exception, the word "organization" means a person or entity.

Options developed at the September meeting for the 1st prong of the exception:

*A1 Only the first tier relationship would be protected under the first prong. (Note: one Member reserved concurrence on this option.)

CONSENSUS reached at September meeting:

An FQHMO des not have to have a Medicare contract to be an "eligible organization under section 1876."

Options clarified at the September meeting for the 2d prong of the exception:

*A2 Only a health plan can be an "organization." (See *4 above)

*B2 Each contracting tier from the MCO (or other payor) through to the provider of services would be protected. (See *6 above.)

*C2 Lower tiers could be protected, but only if protected above.

Third issue in *GROUP:

* *If exception only applies to the first tier, is everything below a kickback?*

Options developed before the September meeting:

*8 Even if the exception only applies to the first tier, it does not mean that the downstream arrangements are necessarily kickbacks. Simply because something does not fall within a safe harbor does not mean that it is per se illegal.

*9 None (don't agree with the premise of the issue).

CONSENSUS reached at September meeting: concur in Option *8

> GROUP OF ISSUES

First three issues in >GROUP (as modified at September meeting):

> *Does the exception cover anything other than what the provider provides directly?*
> *Do the items or services need to be "necessary" ?*
> *Who is an entity or individual providing services and do the services need to be medical in nature or can they be other?*

Options developed before the September meeting:

>1 Only what the provider provides directly or is financially responsible for (subcontract).

>2 Whatever the provider
- provides directly
- is financially responsible for
- can be rewarded for.

>3 Under part II of the exception all of the items and services that the provider provides directly or is financially obligated to provide are protected.

>4 The exception should apply to items and services the contractor is obligated to provide according to the terms of the contract, even if they are not listed with detailed specificity. Requirements should be reasonable and in no case more stringent than those required under the discount safe harbors in current law.

>5 The items and services must be listed specifically in the written agreement to be included within the exception and must be medically necessary.

>6 The items and services must be medical items, devices, supplies, or services paid for in whole or in part by a Federal health care program and provided to a health plan enrollee, where the payments for such items or services are covered by such contract or agreement.

>7 An entity or individual providing services should be defined broadly. Their services may not be exclusively medical in nature.

>8 The exception covers services that the provider provides directly, services that the provider is responsible for arranging for and services for which the provider is at risk.

>GROUP (cont.)

>9 A determination of medical necessity need not be made as one condition for qualifying for the exception. The written agreement does not need to specifically list the services as long as the services covered under the agreement are written with sufficient specificity that the parties understand the serves that need to be provided under the agreement.

>10 For purposes of the second part of the exception, an entity or individual providing services refers to any individual or entity that contracts to provide or arrange for health services.

Issues regarding the 2d prong, as clarified at the September meeting:

> *Which of the following categories of items or services, or a combination thereof are covered by the 2d prong of the exception:*

Category 1. *Those the individual or entity provides directly by employees.*
Category 2. *Those the individual or entity is financially responsible for (including subcontracts if the individual or entity pays the subcontractor, the MCO pays the subcontractor on behalf of the individual or entity, or the subcontractor is paid by reinsurance the individual or entity has obtained).*
Category 3. *Those for which the individual or entity does not receive payment but for which the individual or entity may be rewarded:*
Subcategory A. *Those where there is a close relationship between the compensation the individual or entity receives and particular items or services.*
Subcategory B. *Those where compensation is tied collectively to efficiencies.*

CONSENSUS reached at the September meeting:

Categories 1. and 2. are covered by the phrase "obligated to provide."

>GROUP (cont.)

Options developed at the September meeting:

>A2 Include all of Category 3.
>B2 Exclude all of Category 3.
>C2 Include Subcategory A. (of Category 3), but not Subcategory B.

Fourth issue from >GROUP:

> *Items or services . . . "obligated to provide" -- does it mean by contract or by statute?*

CONSENSUS reached at July meeting:

"Obligated to provide" means obligated by the written agreement.

●**GROUP OF ISSUES** (Note: the Committee agreed these are 2d prong issues.)

- *Is "substantial financial risk" interpreted broadly (generalized test) or narrowly (bright line test)?*
- *Can "substantial financial risk" be defined in nonnumerical terms to allow flexibility in MC arrangements but preserve not encouraging overutilization?*
- *What is the effect of pooling risk on whether it's "substantial financial risk"?*

Options developed before the September meeting:

●1 Substantial financial risk should be expressed in terms of the percentage of net revenue at risk. This percentage should be set at 25% or higher (on an actuarially sound basis) because it seems that such a percentage is necessary in order to have physicians change their behavioral patterns.

●2 Substantial financial risk should be defined to be such risk as will provide a disincentive to provide more services or items.

●3 Substantial risk should be defined in nonnumerical terms to assure that its application will be relevant to risk arrangements that may not exist now but could be developed in the future.

●4 For any specific arrangement to fall within the safe harbor, each arrangement would have to put the provider at substantial financial risk.

●5 "Substantial financial risk" should be interpreted broadly through a generalized test.

●6 "Substantial financial risk" should be interpreted narrowly as a bright line test.

●7 "Substantial financial risk" can be defined in nonnumerical terms to allow flexibility in MC arrangements but preserve not encourage overutilization.

●8 The pooling of risk reduces the amount of risk, which may or may not result in a risk arrangement no longer considered substantial financial risk.

●**GROUP (cont.)**

Option for resolving the third issue (pooling), as modified at September meeting:

●A The risk within each written agreement must be "substantial financial risk."
(Note: the Committee reached Qualified Consensus to adopt this option.)

Options for resolving the first two issues developed at September meeting:

●A Any risk that is downside (foregoing something that the individual or provider might otherwise be entitled to, such as an agreed to fee) would be considered substantial.

●B Two components: 1) have a requirement for a bonus, withhold, or other incentive for efficient behavior and state the principles behind this; and 2) include an element to add credibility (for example, actuarial soundness to prevent a "sham")--a recognizable standard.

●C Hybrid test that would construct a bright line test to protect some arrangements, and then set out principles that could be used to analyze other arrangements (for example, whether the arrangement is commercially reasonable).

●D Look at the intended purpose and effect of the arrangement regarding cost and quality, and then look at the actual effect of the arrangement, setting out factors for analyzing it.

●E Two parts, with capitation covered and a "quantity-based" test, the purpose of which is to define the degree of incentive needed to prevent overutilization, which could vary by type and size of provider.

●F Combination of: A. Bright line tests that you could meet to be protected; and B. A series of factors that, if met, would also protect the arrangement.

+ GROUP OF ISSUES: (Note: these are 2d prong issues.)

+ *What is "risk sharing"? [Does] straight capitation sufficiently constitute risk sharing?*

+ *What is a risk sharing arrangement?*

Options developed before the September meeting:

+1 A risk sharing arrangement is one in which at least some "real" risk is transferred to a second party. The first party need only retain ultimate liability for the services. For example, in a straight capitation from an MCO to a capitated primary care provider, almost all of the risk for primary care services has been transferred to the provider. However, if the provider fails to provide the required care under the agreement with the MCO, the MCO remains responsible to find another provider to provide primary care services.

+2 Risk sharing refers to any arrangement that includes the transfer of risk from one entity to another entity. Straight capitation constitutes risk sharing.

Option as modified at the September meeting:

+A A risk sharing arrangement is one in which at least some "real" risk is transferred to or shared with a second party. The first party need only retain ultimate liability for the services. For example, in a straight capitation from an MCO to a capitated primary care provider, almost all of the risk for primary care services has been transferred to the provider. However, if the provider fails to provide the required care under the agreement with the MCO, the MCO remains responsible to find another provider to provide primary care services.
(Note: The Committee reached a Qualified Consensus to adopt this modified option.)

@ GROUP OF ISSUES:

@ *To be covered by the second prong [of the exception], must the specific items or services provided be covered by a risk sharing arrangement?*

Options developed before the September meeting:

@1 To be covered by the exception, the specific items or services provided must be covered by a risk sharing arrangement.

@2 To be covered by the second prong (of the exception), the specific items or services need not necessarily be health services. (Note: this option was withdrawn.)

 # GROUP OF ISSUES:

What constitutes a "written agreement" (terms, s.a. services, duration . . .)?
Do the items or services have to be specifically listed in the written agreement to be subject to the exception? (Moved from >GROUP.)

Options developed before the September meeting:

#1 A written agreement must meet the following requirements:
(1) set out in writing and signed by the parties
(2) specifies the items and services covered by the agreement
(3) specifies the intervals at which distributions are paid
(4) specifies the formula for calculating incentives/penalties
(5) lasts at least one year
(6) the capitation is set in advance, is consistent with actuarially sound calculations in arms-length transactions and is not determined in a manner that takes into account the number of Medicare beneficiaries being served under the contract.

#2 A written agreement should be defined to include only those elements that are necessary to assure that it can be determined that the relationship between an organization and an entity is not a sham. The number of these elements is few and should not exceed those required under the existing safe harbors.

#3 A written agreement is a legally binding written contract.

Options developed or modified at the September meeting:

#A A written agreement must meet the following requirements:
(1) set out in writing and signed by the parties
(2) specifies the items and services covered by the agreement
(3) specifies the intervals at which distributions will be made
(4) specifies the formula for calculating incentives/penalties
(5) lasts at least one year
(6) the methodology for determining compensation is set in advance, is consistent with actuarially sound calculations in arms-length transactions, and is not determined in a manner that takes into account the number of Federal fee-for-service beneficiaries being served under the contract.

#B Substitute for "specifies the items or services" (in the option above) a general descriptor of the services that would be sufficient to describe the services under community standards.

~ GROUP OF ISSUES:

~ *Difference, if any, between withhold and bonus.*

~ No difference because a withhold could always be made to look like a bonus and vice versa**.**

~ There is no meaningful distinction between a withhold and a bonus. Both should be recognized as elements of legitimate risk sharing arrangements between organizations and entities.

CONSENSUS reached at September meeting:

For purposes of this rule, there is no functional difference between a withhold and a bonus.

D GROUP OF ISSUES

D *What's the significance of "or combination" thereof?*

CONSENSUS reached at July meeting:

The significance of "or a combination" thereof is that the risk can be for items, services, or both.

Q GROUP OF ISSUES:

Q *How do you incorporate the evaluation of quality in IV [of the factors to consider] into the criteria for "substantial financial risk"?*
Q *Integration of "downstreaming" and quality of care as criteria*
Q *Is quality of care an anti-kickback concern?*
Q *How do you incorporate the evaluation of quality in the factors to be considered for "substantial financial risk"?*

Options developed before the September meeting:

Q1 Yes, quality of care is an antikickback concern. "Substantial financial risk" should include meaningful incentives for quality of health care services. Financial incentives for quality of care should be reflected in the written agreement in the form of financial contingencies connected to measurable outcomes. Incentives should be evidenced by requirements for efforts to evaluate and improve the quality of care given and publication of the same; the collection and submission of encounter data, patient and provider satisfaction data, and complaint and appeals use and outcome data; and the disclosure of the risk sharing arrangement to patients.

Q2 Quality factors can be incorporated by denying the exemption where the licensed entity has been found to be out-of-compliance with Federal or state quality standards or where the MCO or other organization that has been delegated the quality oversight function has found that the provider fails to meet quality standards imposed by the MCO or the delegated entity. Quality of care is not an anti-kickback concern [although it is critically important, and therefore the anti-kickback law should not be extended to include quality factors except to the limited extent stated above].

Options developed/modified at the September meeting:

QA Written agreement must include incentives to meet quality standards. (Possible modification: incentives could merely incorporate existing standards, rather than adding new ones.)

QB Address quality concerns as part of defining what is "substantial financial risk"--by not setting the level too high or by requiring that something be in the contract if the level is set high so as to cause a concern for underutilization.

QC Say that, if a provider is out of compliance with a quality standard, the exception would not apply.

QD The written agreement would include incentives to meet existing standards.

Q GROUP (cont.)

QE If there is an existing law or accreditation standard that applies to the provider, accept that; require that there be an incentive in the written agreement only where no existing law or accreditation standard applies; also, you would not need an incentive for any group that contracts with an MCO that is accredited or subject to existing laws on quality, because the MCO would have an obligation to ensure that quality standards were met.

QF Add nothing new, but say that the overall quality test would be whether the arrangement provides an incentive to overutilization.

QG Have in the rule that quality of care oversight must flow down.